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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,061	05/08/2001	Christer Nordstedt	033315-002	1927

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/850,061

Applicant(s)

Nordstedt et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/03
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18 and 35-41 is/are pending in the application.
- 4a) Of the above, claim(s) 12, 15-17, 35, 36, 39, and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 18, 37, 38, and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION***Status of Claims***

1. Amendment and response to restriction requirement filed 03/24/2003 is acknowledged. Claims 1-11, 19-34 are canceled. Claims 38-41 are added. Claims 12-18, 35-41 are pending. In response to restriction requirement, applicant elected Group II, drawn to method to inhibit polymerization of amyloid β peptide. Examiner agrees that claims 37, 40 should be rejoined, but disagrees that claims 35,36,39,40 should be included into the elected Group II. In regard to claims 35,36,39 inhibition of polymerization of amyloid β peptide is not equivalent to treatment particular diseases which have variable mechanisms of development and etiology. In particular, in regard to treatment of amyloidosis (claim 39), there are several types of amyloidosis (three major types and several less common forms) having different origin¹. In regard to claim 40, the claim is drawn not to polymerization of β peptide itself, but polymerization of β peptide to a ligand. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 35,36,39,40 are withdrawn

¹type A is related to variable region of an immunoglobulin light chain, and occurs in primary amyloidosis and in amyloidosis associated with multiple myeloma; the second type has a unique N-terminal sequence of a nonimmunoglobulin protein called AA protein and occurs in patients with secondary amyloidosis; the third type, which is associated with familial amyloid polyneuropathy, is usually a transthyretin (prealbumin) molecule that has a single amino acid substitution. Other hereditary amyloids have been found to consist of mutant gelsolin in some families, mutant apolipoprotein A-I in several others, and other mutant proteins in hereditary cerebral artery amyloid. The amyloid found in the histopathologic lesions of Alzheimer's disease consists of β proteins.

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from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 35,36,39,40 is requested.

In regard to election of species, Examiner acknowledges that elements of structure of SEQ ID No. 8 (HHQKLVFF) read on particular values of the radicals claimed. However, Examiner maintains, as was explained to Attorney Jay F. Williams during telephone conversation maintains that peptide SEQ ID No. 8 is not identified as particular species in the claims and, therefore, there are no claims reading specifically on this compound. While there are claims reading on the same values of Y', Z', R' and R2 (claims 13,14,18) there are no claims reciting particular moiety A' as in SEQ ID No. 8 (HHQ moiety). Therefore, neither this particular moiety, nor peptide HHQKLVFF, are addressed in this Office action. Claims reading on values of radicals of compound SEQ ID No. 8, claims 13,14,18 are addressed as reading on the elected species; generic claims 37,38,41 are addressed to the extent they read on the elected species.

Claims 12,15-17 are withdrawn from consideration as drawn to non-elected species. Examination of non-elected species will be proceeded to once the claims drawn to the method of use of the elected species is deemed allowable.

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Claim Rejections - 35 USC § 102 and 103.

2. Claim 40 is rejected under 35 U.S.C. 102(e) as clearly anticipated by Findeis et al. (US 5,854,204).

Findeis describes agents which modulate β -amyloid peptide aggregation. In particular, establishing the five amino acid subregion of A β peptide sufficient for inhibitory activity of a β -modulator compound, the reference specifically points at A β 16-20 region, which is KLVFF moiety (note this moiety (underlined) in the elected species HHQKLVFF²). See Example 9, cols. 56-57. Particular examples of peptides with KLVFF moiety having inhibitory activity on β -amyloid peptide aggregation (reflected in change in lag time, and/or reduction in turbidity, and/or inhibition in extension assay) are shown in Table V (cols. 61-62). See, for example, compounds PPI-377, PPI-386, PPI387, PPI-405.

3. Claims 37, 38, 13, 14, 18 are rejected under 35 U.S.C. 103(a) as obvious over Findeis et al. The reference is applied as discussed above. The reference teaches pharmaceutical compositions of the modulator peptides but does not teach, specifically, their therapeutic administration. However, as inhibition of β -AP

²HHQKLVFF itself is addressed in col. 57, line 34 of the reference as A β 13-20 fragment.

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aggregation is a desirable therapeutic effect, such use will be obvious to one skilled in the art.

Claim Rejections - 35 USC § 112, first paragraph.

4. Claim 37 is rejected under 35 U.S.C. 112 first paragraph, because the specification, while being enabling for the use of peptides for inhibiting, or treating to inhibit, does not reasonably provide enablement for a method of treatment to prevent fibril formation. The burden of enabling a method of prevention of a disorder would be greater than that of enabling a method of treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition. Further, the specification does not provide guidance as to how one skilled in the art would go about screening those patients susceptible to fibril formation within the scope of the presently claimed invention. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in preventing the fibril formation. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

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Conclusion.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 22, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

